

AMENDMENTS TO THE CLAIMS

This listing replaces all prior versions and listings of claims in the application.

Listing of Claims

1-25. (Cancelled)

26. (Currently Amended) A pharmaceutical composition for percutaneous administration comprising ~~4-hydroxy tamoxifen~~ a pharmaceutically active agent and at least one fatty acid ester penetration enhancer, wherein the pharmaceutically active agent consists essentially of 4-hydroxy tamoxifen.

27. (Previously Presented) A composition according to claim 26, wherein the pharmaceutical composition is a hydroalcoholic gel.

28. (Previously Presented) A composition according to claim 26, wherein the pharmaceutical composition comprises a penetration enhancer, an aqueous vehicle, an alcoholic vehicle and a gelling agent.

Claims 29-30 (Cancelled)

31. (Previously Presented) A composition according to claim 28, wherein the pharmaceutical composition comprises: a) about 0.001% to 1.0 % by weight of 4-hydroxy tamoxifen, b) about 0.5% to 2% by weight of isopropyl myristate, c) about 65% to 75% by weight of alcohol, d) about 20% to 35% by weight of aqueous vehicle, e) about 1.0% to 5% by weight of gelling agent, wherein the percentage of components are weight to weight of the composition.

32. (Original) A composition according to claim 31, wherein the 4-hydroxy tamoxifen constitutes about 0.01%, 0.02%, 0.03%, 0.04%, 0.05%, 0.06%, 0.07%, 0.08%, 0.09%, or 0.10% by weight of the composition.

33. (Original) A composition according to claim 31, wherein the isopropyl myristate constitutes about 0.5%, 0.6%, 0.7%, 0.8%, 0.9%, 1.0%, 1.1%, 1.2%, 1.3%, 1.4%, 1.5%, 1.6%, 1.7%, 1.8%, 1.9% or 2.0% by weight of the composition.
34. (Original) A composition according to claim 31, wherein the alcohol is ethanol or isopropanol, and constitutes about 65% to 75% by weight of the composition.
35. (Original) A composition according to claim 31, wherein the aqueous vehicle is a phosphate buffered solution, and constitutes about 25% to 35% by weight of the composition.
36. (Original) A composition according to claim 31, wherein the gelling agent is a polyacrylic acid, hydroxypropylcellulose or other cellulose derivative, and constitutes about 1.0% to 5% by weight of the composition.
- Claim 37 (Canceled)
38. (Original) A composition according to claim 31, which is packaged in a unit dose packet or in a multiple dose container with a metered pump.
39. (New) A pharmaceutical composition for percutaneous administration comprising a pharmaceutically active agent and at least one fatty acid ester penetration enhancer, wherein the pharmaceutically active agent consists of 4-hydroxy tamoxifen.
40. (New) A composition according to claim 39, wherein the pharmaceutical composition is a hydroalcoholic gel.
41. (New) A composition according to claim 39, wherein the pharmaceutical composition comprises a penetration enhancer, an aqueous vehicle, an alcoholic vehicle and a gelling agent.

42. (New) A composition according to claim 39, wherein the pharmaceutical composition comprises: a) about 0.001% to 1.0 % by weight of 4-hydroxy tamoxifen, b) about 0.5% to 2% by weight of isopropyl myristate, c) about 65% to 75% by weight of alcohol, d) about 20% to 35% by weight of aqueous vehicle, e) about 1.0% to 5% by weight of gelling agent, wherein the percentage of components are weight to weight of the composition.

43. (New) A composition according to claim 42, wherein the 4-hydroxy tamoxifen constitutes about 0.01%, 0.02%, 0.03%, 0.04%, 0.05%, 0.06%, 0.07%, 0.08%, 0.09%, or 0.10% by weight of the composition.

44. (New) A composition according to claim 42, wherein the isopropyl myristate constitutes about 0.5%, 0.6%, 0.7%, 0.8%, 0.9%, 1.0%, 1.1%, 1.2%, 1.3%, 1.4%, 1.5%, 1.6%, 1.7%, 1.8%, 1.9% or 2.0% by weight of the composition.

45. (New) A composition according to claim 42, wherein the alcohol is ethanol or isopropanol, and constitutes about 65% to 75% by weight of the composition.

46. (New) A composition according to claim 42, wherein the aqueous vehicle is a phosphate buffered solution, and constitutes about 25% to 35% by weight of the composition.

47. (New) A composition according to claim 42, wherein the gelling agent is a polyacrylic acid, hydroxypropylcellulose or other cellulose derivative, and constitutes about 1.0% to 5% by weight of the composition.

48. (New) A composition according to claim 42, which is packaged in a unit dose packet or in a multiple dose container with a metered pump.